SEP 23 2002

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Orthopedic Sciences, Inc. 6080 Center Drive, 6th Floor Los Angeles, CA 90045
Official Contact:	James K. Brannon, M.D. President/CEO Telephone (310) 242-6643 FAX (310) 242-6603
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Plate, fixation, bone
Trade/Proprietary Name:	Hip Tool™ Implant
Common Name:	Bone plate

DEVICE CLASSIFICATION

Single/multiple component metallic bone fixation appliances and accessories have been classified by FDA as Class II devices, as shown in 21 CFR 888.3030. The device is reviewed by the Orthopaedic and Rehabilitation Devices Panel and the Product Code for the device is HRS.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Hip Tool™ Implant complies include American Society for Testing and Materials (ASTM) designation F138, *Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)* and ANSI/AAMI/ISO 11137, *Sterilization of Health Care Products - Radiation Sterilization.*

INTENDED USE

The Hip Tool™ Implant is intended to stabilize a bone graft within the femoral head and neck to assist healing of an intraosseous fracture.

DEVICE DESCRIPTION

Design Characteristics

The Hip Tool™ Implant is a component of the Hip Tool™ Bone Graft Stabilization System (BGSS). The complete system consists of the Hip Tool™ Implant, a trial implant, and a series of manual surgical instruments (Class 1, exempt, not a subject of this submission) intended to assist in core decompression of osteonecrotic bone in the femoral head. The Hip Tool™ Implant consists of a bone plate and barrel and a graft compression screw and locking screw. The plate is attached to the femur using standard 4.5 mm cortical bone screws. The Hip Tool™ Implant is intended to stabilize a bone graft that is placed during the surgical procedure.

Material Composition

The Hip Tool™ Implant is made from 316L medical grade stainless steel that meets ASTM designation F138, *Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)*. The use of Type 316L stainless steel is widespread in commercially distributed, permanently implanted medical devices and the material is widely considered to be biocompatible.

EQUIVALENCE TO MARKETED PRODUCT

Orthopedic Sciences, Inc. submits the following information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Hip Tool™ Implant is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices, and to a surgical procedure that is a currently accepted protocol.

The design and functional characteristics of the Hip Tool™ Implant and the predicate procedures and devices are substantially the same. They function by stabilizing a fracture to promote healing of cancellous bone. The closest predicate is a surgical procedure detailed by Urbaniak and Harvey (J Am Acad Orthop Surg 1998; 6:44-54) which is a currently accepted protocol. Both the use of the Hip Tool™ BGSS and this procedure utilize core decompression and cancellous bone grafting to stabilize the resultant intraosseous fracture.

Other predicate bone plate based devices are the Synthes Distal Femur Plate (DFP) System (K982222), Synthes Locking Condylar Plate (LCP) System (K000066), BioPro Wujin #3 femoral bone plate (K011459), DuPuy ACE Medical Trochanteric Side Plate (K970503), Stryker Plating System Basic Fragment Set (K012162), Metagen High Tibial Osteotomy System (K963700), Smith

& Nephew Bone Plate System (K993106), Syntec-Taichung Medical Instruments Non-sterile Titanium Alloy Mini Plate (K983988) and Ferguson Medical Orthopedic Plate System (K972219). All of these marketed devices provide stabilization of bone fragments to promote healing of bone. In particular, the Synthes Distal Femur Plate includes a threaded hole whereby the head of the bone screw can be locked to the plate to create a fixed angle. This locking mechanism provides additional stability to the bony fragments when the screw is engaged in the bone. The Hip Tool similarly has a locking mechanism that is intended to stabilize bone fragments.

Predicate devices used to stabilize fractures of the femoral neck are the Osteonics Osteo Compression Hip Screw System (K982553), and the Ferguson Medical Fixano D.S.S. System for Osteosynthesis of Unstable Femoral Neck Fractures (K970258). These devices provide stabilization of femoral neck fractures to promote healing of bone.

Other devices with similar intended use include the MacroPoreOS Protective Sheet (K994158), Synthes Resorbable Meshes and Sheets (K003788) and Biomet LactoSorb Panels and Fasteners (K011139 and K984390). These devices maintain position of weak bony tissue, bony fragments, bone grafts and bone graft substitutes, and morselized bone graft to promote healing of bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Orthopedic Sciences, Inc.
c/o Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K022139
Trade/Device Name: Hip Tool Implant
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 1, 2002
Received: July 2, 2002

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

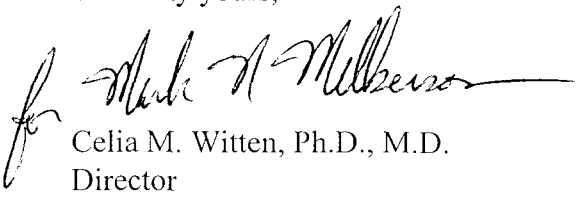
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Hip Tool™ Implant

K022139

Indications for Use:

The Hip Tool™ Implant is intended to stabilize a bone graft within the femoral head and neck to assist healing of an intraosseous fracture.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use____

Mark N Milhern

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K022139